

Instruction for Use

EsCom® 250



Light-cured Restorative Composite Resin

General Information

EsCom®250 is the polymer-based dental restorative material. It can be light-cured intra orally for anterior and posterior restoration including occlusal surface. Filler size ranges from 16nm to 1.2µm. Various shades of A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3 and TW for esthetic restoration are provided. All shades of EsCom®250 are radio-opaque.

Intended Purpose

EsCom®250 is a light-cured dental composite resin which is applied directly to the anterior and posterior teeth for restoration of dental patients.

Intended User

Dentist who has experience of dental light-cured composite restoration

Target patient group

Dental patients

Classification

Type1, Class 2, Group1 according to ISO 4049

Composition

- Organic Matrix: Bis-GMA, UDMA, TEGDMA
- Inorganic Fillers: 16nm ~ 1.2µm zirconia filler, Ba glass, fumed silica, 60 % by volume.
- Additives: Initiator, Catalyst, Stabilizer, Others

Performance characteristics

- Depth of cure: ≥1.0mm for opaque shade and ≥1.5mm for other shade
- Water sorption: ≤ 40 µg/mm³
- Solubility: ≤ 7.5µg/mm³
- Flexural strength: ≥ 80 MPa
- Radiopacity: Equal or greater than the same thickness of aluminium

Precautionary Information

- Check the expiration date and appearance condition of product and package. DO NOT use after the indicated expiration date.
- Observe the instruction for use after being well acquainted with the instruction for use.
- Do not use if the material has been cured.
- When the product has any problem user should stop using it and contact with our company.

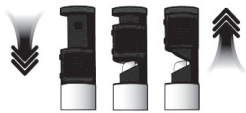
Application

Preparation

- Teeth should be cleaned with pumice and water to remove surface stains.
- Shade Selection:** Before isolating the tooth, select the appropriate shade(s) of restorative material. Refer to the shade guide provided
- Isolation:** Place a rubber dam, if necessary.

Restoration

- Cavity Preparation:** Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.
- Pulp Protection:** Apply a calcium hydroxide pulp protector such as Base-it®. If needed. DO NOT USE EUGENOL-BASED MATERIALS to protect the pulp as these materials will inhibit curing of EsCom®250.
- Adhesive System:** It is recommended that suitable etchant on the market like as Spident® FineEtch® is applied and rinse thoroughly according to the manufacturer's instruction and dental bonding agent on the market like as Spident® EsBond® is applied and then light-cured according to manufacturer's instructions.
- Dispensing the composite:** Follow the instructions below according to the resin application method.
 - Syringe:** Open the cap of syringe and dispense the necessary amount of restorative material from the syringe using a dental instrument by turning the handle clockwise slowly. Close syringe cap immediately. If not used immediately, the dispensed material should be protected from light. It could be polymerized by ambient light or the dental operating light.
 - Single-Dose Capsule:** Insert capsule into a capsule dispensing gun. Extrude restorative directly into cavity.
 - EZ SLIDE:** Slide the cap of syringe upper side and dispense the necessary amount of restorative material from the syringe using a dental instrument by turning the handle clockwise slowly. Close slide cap immediately. If not used immediately, the dispensed material should be protected from light. It could be polymerized by ambient light or the dental operating light.



<How to use EZ SLIDE cap>

- Placement:** For optimum results, apply EsCom®250 in layers, not exceeding 2 mm and adapt with a suitable instrument. Sufficient exposure to the curing light prevents incomplete polymerization. Use the dental light curing unit with a minimum intensity of 1200 mW/cm² in the 440-490nm range of wave length. Recommended exposure time is 20 sec.
- Finishing:** Remove excess material with suitable finishers or fine diamonds bur after polymerization. Remove proximal excess with diamond or tungsten carbide finishers, finishing strips, or flexible finishing discs.

- Adjust Occlusion:** Check occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.
- Polishing:** Use silicone polishers as well as polishing discs and polishing strips to polish the restorations to durable high gloss.

Side effect

Secondary caries, sensitivity, debonding. There are three known side effects associated with composite resins, but they may be caused by the operator's technique, patient's oral hygiene, or use with other devices.

IFU#194404(R 03/23)



Manufacturer

SPIDENT CO., LTD. www.spident.co.kr
203 & 312, Korea Industrial Complex, 722, Gojan-Dong,
Namdong-Gu, Incheon, Korea 405-821
TEL. +82-32-821-0071 FAX. +82-32-821-0074

EU representative

AR EXPERTS B.V. (tradename : CE Medical)
Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands
TEL. +31 (0)85 007 32 20

Contraindication

This material contains methacrylic monomer. Some patients can cause allergic reaction to monomer such as hypersensitivity reaction, irritation, or stomatitis. **Do not use this material for patients allergic to or hypersensitive to methacrylic monomers.**

Caution

- This material is medical device for licensed dental care professionals (Dentist) only.
- Avoid contact of this material with eyes, mucosal membrane, skin and clothing.
- If this material comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- Use a rubber dam to protect the throat.
- If this material causes an allergic reaction or oversensitivity, discontinue its use immediately and take action emergency.
- It must be reported to the authority any serious side effects and accidents that may occur.
- Colour stability is not claimed when contravening the storage & use in this document.
- In case of multi-dose syringe, it should be used cleanly to prevent cross-contamination.
- Conditions of teeth, anesthesia, and dentist's techniques can affect the safety and performance of the product.

Storage & Use

- Store at a temperature between 2 - 27°C.
- If refrigerated, allow product to reach appropriate temperature to operate prior to use.
- Do not expose the material to elevated temperatures, or to intense dental operating light. Polymerization may be started.
- Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life.
- Shelf life of EsCom®250 is 36 months.
- See outer package for expiration date.
- Do not store materials in proximity to products containing Eugenol.
- In case of multi-dose syringe, EsCom®250 can be used until resin is used up within the expiration date.

Sales unit

Sales unit	Components	Shade provided
4g EsCom®250 Syringe, EsCom®250 EZ SLIDE	• 4g single syringe • Instruction for use 1ea	A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3, TW
EsCom®250 Capsule	• 0.25g single dose capsule 20ea • Instruction for use 1ea	A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3, TW
EsCom®250 System Kit	• 4g syringe 5ea • Etchant tip 4ea • FineEtch®-37 5ml • EsBond® Refill 5ml • Dispensing Dish 1ea • Tip Holder 1ea • Micro Tip Application 30ea • Shade guide 1ea • Instruction for use for EsCom®250, FineEtch®, EsBond®	According to the customer's request
EsCom®250 Syringe Kit	• 4g syringe 8ea • Shade guide 1ea • Instruction for use 1ea	According to the customer's request
EsCom®250 EZ SLIDE System Kit	• 4g EZ SLIDE 5ea • Etchant tip 4ea • FineEtch®-37 5ml • EsBond® Refill 5ml • Dispensing Dish 1ea • Tip Holder 1ea • Micro Tip Application 30ea • Shade guide 1ea • Instruction for use for EsCom®250, FineEtch®, EsBond®	According to the customer's request
EsCom®250 EZ SLIDE Syringe Kit	• 4g EZ SLIDE 8ea • Shade guide 1ea • Instruction for use 1ea	According to the customer's request

Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident® MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Spident®'s sole obligation shall be repair or replacement of the Spident®'s product.

Limitation of Liability

Except where prohibited by law, Spident® will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.
Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Disposal

It should be handled according to local laws and regulations

Other Devices used together

- Dental etchant
- Dental bonding agent
- LED curing lights
- Dental instrument
- Dental bur

Location of SSCP: EUDAMED

Pictogram

Conformity with	CE Comunaute Europeenne	EC REP	Authorized representative in the European Community		
23°C	Temperature limit	LOT	Batch code	Importer	
Sunlight	Keep away from sunlight	Calendar	Date of manufacture	Distributor	
Umbrella	Keep dry	Hourglass	Used-by date	Caution	
MD	Medical Device	Factory	Manufacturer	Consult Instructions for use	
Rx Only	Federal law prohibits dispensing without a prescription				

※ If there has been occurred any serious accident in relation to the our device released in market, the quality management representative of our company will notify the Notified Body & the competent authority of any serious accident in accordance with the vigilance procedure.